



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
State Programs Branch

Food and Drug Administration  
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August 7, 1996

Mr. Paul S. Anderson  
Director, Shellfish Sanitation Program  
Maine Department of Marine Resources  
Boothbay Harbor Laboratory  
McKown Point Road  
W. Boothbay Harbor, ME 04575

Dear Mr. Anderson:

Enclosed is the trip report which describes findings of the inspections and file reviews comprising a part of the evaluation of the Maine Shellfish Sanitation Program. The items which do not meet the satisfactory compliance requirements of the National Shellfish Sanitation Program are identified on the worksheets.

We are happy to report that there were no category 2A or 2B deficiencies found. Recommendations for program improvements were discussed at the closeout meetings. There are additional recommendations in Section VII of the trip report.

Part of the purpose of the field work was to restandardize Ms. Fitzpatrick as the State Standardization Officer. We are pleased to note that she passed the standardization exercise and her standardization is renewed for three years. We will forward her certificate to you as soon as we receive it from the Center for Food Safety.

My congratulations to you and your staff on the excellent progress made in a short time.

Please do not hesitate to contact me if you have any questions.

Sincerely,

David G. Field  
Director

Enclosure

pc: Commissioner Alden  
Ms. Fitzpatrick  
HFS - 637  
HFC - 152



STATE PROGRAMS BRANCH  
NORTHEAST REGION  
**MEMORANDUM**

DATE **August 6, 1996**

FROM **Ira J. Somerset, Regional Shellfish Specialist**

SUBJECT **Trip Report**

TO **Maine Files - Focus '96**

**I. Purpose and Time Period**

A review of the growing area survey and classification element was conducted between June 5 and June 13 in the Lamone and Boothbay Harbor Laboratories.

A review of the Marine Biotoxin Program element was conducted on June 10 in the Boothbay Harbor Laboratory.

A review of the Plant Sanitation Program element was conducted on June 19, 20, and 23.

The information gathered during these field efforts was evaluated between July 16 and August 2, 1996.

This evaluation was conducted in accordance with the protocol and procedures of Focus '96 and subsequent modifications issued by the Office of Seafood.

**II. Scope**

There are 45 designated growing areas in Maine, of which six were evaluated under Focus '96. Three areas from each half of the state were evaluated at each laboratory. In addition, followup to the corrections of deficiencies previously found was conducted at each laboratory.

The current Marine Biotoxin Contingency Plan and files were reviewed for consistency with NSSP requirements.

The Plant Sanitation Program evaluation consisted of restandardizing the State

Standardization Officer, which resulted in the inspection of five plants used for program evaluation and standardization.

### III. Persons Contacted

Lamoine Laboratory: Paul Anderson and John Fendl

Boothbay Harbor Laboratory: Paul Anderson, Fran Pierce, Jan Barter, Hilton Applin, and Laura Livingston for the growing area survey and classification element evaluation and John Hurst for the marine biotoxin element.

Plant Sanitation: Amy Fitzpatrick

### IV. Findings

Copies of the worksheets are attached, as are compilations of cited deficiencies.

#### A. Growing area survey:

The Compliance Program required followup to all deficiencies cited during the Focus '94 and Focus '95 evaluations and verification of the corrections. The response to FDA for the Lamoine Laboratory was contained in a letter dated July 11, 1995, and the Boothbay Harbor findings were addressed in a letter of 12/7/95. Each item is addressed below:

**Area EA** - There is a new MOU for the conditional area management based on Appendix K. The sanitary survey is in draft. The shoreline survey was conducted in the fall of 1995, and is in the final draft stage as is the sanitary survey. The annual update addresses all items required. There is no statement in the management plan of how frequently the plan will be evaluated, nor was there a statement in the annual update assessing how well it worked.

**Area EF** - There is a written annual update and a triennial reevaluation, and a resurvey in progress. The conditionally restricted portion was included in the resurvey but remains closed. The field work is about 20% completed. There is no statement in the management plan of how frequently the plan will be evaluated, nor was there a statement in the annual update assessing how well it worked.

**Area EH** - Being resurveyed. Determinations of A/P and D/I will be made (the last survey was conducted prior to that requirement). Annual update has been written.

**Area EH** - triennial reevaluation in progress. Annual update completed 1/19/96.

**Area EL - (Followup and rereview) -** A complete resurvey was conducted in 1995 and the annual update was completed. The conditional area has been reclassified as prohibited based on the resurvey. Review of the file in accordance with Focus '96 procedures showed no deficiencies.

**Area EP - (Followup and rereview) -** The sanitary survey had been written prior to current requirements. The area was resurveyed and the report written in the new format. Review of the file in accordance with Focus '96 procedures showed no deficiencies.

**Area EN - Review -** Review of the file in accordance with Focus '96 procedures showed no deficiencies.

**Area A -** Additional samples to meet the minimum requirements have been collected and analyzed, the conditional area management plans are being revised to include a statement in the management plan of how frequently the plan will be evaluated, and an evaluation statement in the annual update assessing how well it worked.

**Area F -** Additional samples to meet the minimum requirements have been collected and analyzed. However, station 6.1, a new station, had a  $P_{90}$  of 57.3 (>49), and does not meet the criteria for an approved area.

**Area G -** The conditional management plan in this file had several deficiencies based on the requirements of Appendix K:  
the boundaries described were the closure lines, not the conditional areas, there was no discussion and data concluding that the events were predictable, (III.B.2),  
there was no prediction of the number of times of occurrence (III.B.3),  
there was no discussion of implementation and enforcement of closures (IV.B and C), and  
there was no statement about the annual evaluation (Sections C.4.d.iv and C.6.d.iv).

**Area I -** The conditional area has been closed, obviating the need for a management plan and its annual review at this time. Additional samples have been collected and analyzed. The marina calculation was questioned during the original review of this area, but no answer was received from CFSAN.

**Area K - (Followup and rereview) -** There were numerous deficiencies in the sanitary and shoreline surveys in this area. To address these deficiencies, three sanitary surveys and a supplement to another were written late in 1994. The one

area surveyed under contract did not show D/I and A/P for sources of pollution on the field sheets. Review of the file in accordance with Focus '96 procedures showed no other deficiencies.

**Area M - (Followup and rereview) -** There were numerous deficiencies in the sanitary and shoreline surveys and the conditional management plans identified in this area in the 1995 evaluation. New shoreline surveys were conducted in areas lacking surveys, and the data will be compiled into one sanitary survey report this year. The sanitary survey is in process for Atkins, Drummore, and Wyman Bays. Areas not meeting the approved area standards have been closed. Annual reviews have been conducted as required. The conditional management plan follows the 1994 (old) format, but contains the criteria and procedures for rainfall closures of Parker Flats. The Squirrel Point portion does not follow the format of Appendix C, but Back River does. The Back River report does not discuss how/why this should be a restricted area. Since the STP's on the Kennebec chlorinate only in the summer, the area will be revisited. Review of the file in accordance with Focus '96 procedures showed no deficiencies.

**Area Q -** There was no Appendix K management plan for the conditional areas, and no annual evaluations of the conditional areas. The conditional management plan in this file had the following deficiencies based on the requirements of Appendix K:

- there was no discussion of implementation and enforcement of closures (IV.B and C), and

- there was no statement about the annual evaluation (Sections C.4.d.iv and C.6.d.iv).

**Area S -** The annual update for this area was written, but the triennial review has not been completed. Station S in Sampson Cove was changed from open approved to rainfall conditional without a sanitary survey to support the change.

**Area T -** The area had not had a sufficient number of samples collected, and the data did not support the classification in portions of the area. The portions of the area without the requisite 30 samples were on the small uninhabited islands. The data and number of samples indicate that the classification is consistent with the intent of the NSSP. DMR will develop a policy for addressing the islands off the coast.

**Area V - (Followup and rereview) -** The deficiency found in this area also related to the island sampling. Additional samples and information indicate the same as in Area T. Review of the file in accordance with Focus '96 procedures showed no deficiencies.

**Summary:** The conditional management plans written at the Boothbay Laboratory are not consistent with the format requirements of Section C.4.d. and C.6.d.; the content requirements in Appendix K Sections IV.B and C (relating to discussion of implementation and enforcement of closures); and Sections C.4.d.iv. and C.6. d.iv. (the statement that the conditional area will be reevaluated annually). The annual evaluations do not assess the effectiveness of the conditional management plan. The sanitary survey of area M did not follow the required format. The P 90 at one station in area F exceeded the allowable for an open area station. An open approved portion of Area S was reclassified to rainfall conditional without a survey to determine the interrelationships and develop the basis for rainfall conditional management of the area. The management plans written at the Lamoine Laboratory are missing the frequency of review statement (Sections C.4.d.iv. and C.6.d.iv), and the annual updates do not assess the effectiveness of the conditional management plans.

**B. Plant sanitation:**

The plant sanitation program element review accomplished the goals of collecting the program element evaluation data and restandardizing the State Standardization Officer. Ms. Fitzpatrick met the requirements of Part II, Appendix E and achieved Standardization Officer status.

The Focus '96 evaluation questions were answered affirmatively, and indicated compliance with the legal basis requirements. The tagging and record keeping requirements of the NSSP were emphasized during the interview and inspections. The DMR rules are virtually the same as the NSSP Manual for tagging and record keeping. The Standardization Officer follows the Appendix E procedures to standardize the state inspectors. It appears that the three inspectors are able to conduct inspections and reinspections at the required frequency.

Although there were deficiencies in tagging and record keeping observed, they were minor (e.g., wrong harvest date on one entry in a firm, entries a few days behind at another firm, the need for one firm to track shellfish sold by its retail store, inclusion of the town with the harvest area). Copies of tags were collected and are attached.

The inspections results are shown on Attachment M. It should be noted that the significant deficiencies that could have caused adulterated product to be marketed were corrected by the state inspector at the time of the inspection. The other deficiencies were referred to the area inspector for followup.

The total number of certified shippers in Maine varies with season, there being an increase in the summer months to nearly 200 firms. For this evaluation and restandardization, the following five plants were inspected:

Perkins Seafood	ME 323 SP
Bayley's Lobster Pound	ME 140 SP
O'Hara Seafood	ME 14 SS
Stillwater Clam Co.	ME 93 SS
Preble Fish	ME 256 SS

The deficiencies noted most frequently were:

- #7 Insect/rodent control (5 times)
- #19 Non-food contact surfaces (5 times)
- #46 Supervision (5 times)
- #4 Premises (4 times)
- #5 Floors (4 times)
- #6 Walls, ceilings (4 times)
- #17 Toxics (4 times)
- #28 Shellstock separated (4 times)
- #47 Records (4 times)

### **C. Marine biotoxins:**

The Focus '95 review of the Biotoxin Monitoring program element found several administrative deficiencies, but took note of the fact that the monitoring program was well-run and protected the public health. A draft contingency plan was submitted for review and comment by FDA, and comments were returned to the DMR. The draft contingency plan and MOU require revision and some modifications. They address all requirements of Section C.8 and the suggested contingency plan of Appendix A except for the followup data section (D) of Appendix A. However, the form and format make them confusing.

### **V. State Action**

During the evaluation, there was discussion of each item that did not appear to meet the NSSP criteria, and why it did not meet the criteria. Notes were taken by Maine personnel where appropriate, and changes promised.

### **VI. State Accomplishments**

The status of the Maine program and recent accomplishments were enumerated in the letter from Paul Anderson to Ira Somerset dated April 18, 1996, and forwarded to all involved FDA offices. The only accomplishment of note since that time is the reclassification of the State Standardization Officer to a higher grade and the continued progress of the survey and classification activities in the Boothbay

Laboratory. The GIS mapping system is being installed rapidly and will make a big difference in all aspects of the shellfish program which rely on determining location of pollution sources, resources, stations, etc. (See attached example.)

## VII. Recommendations

### Growing area survey and classification :

- \* Revise the shoreline and sanitary survey reports so they are consistent in format between the two laboratories,
- \* Revise the shoreline and sanitary survey reports so they are consistent in meeting the NSSP requirements for form and content,
- \* Revise the management plans for conditional areas, MOU's, and other documents so they are consistent in meeting the NSSP requirements for form and content,
- \* Include the annual review statements in the conditional management plans,
- \* Review and evaluate the conditional management plans annually as required, and
- \* Develop an island sampling policy.

### Marine biotoxin management:

- \* Revise the MOU and Contingency Plan per discussions at the closeout meeting.

### Plant inspection and certification:

- \* Followup on the deficiencies noted during the inspections.
- \* The Standardization Officer should allocate time to work with each of the area inspectors in their own areas.
- \* Develop a program of having the inspectors work with each other for cross-training and additional experience.